

Part 2 – Remarks

This Amendment and Response is responsive to the first substantive Office Action mailed October 29, 2007. A Petition for Three Month Extension of Time and the fee therefor accompanies this Amendment and Response, thereby extending the time for response to April 29, 2008.

In the October 29 Office Action, claims 49-87 were withdrawn from consideration as being directed to a non-elected invention; the information disclosure statement of February 9, 2004 was objected to; claims 1 and 31 were objected to because of informalities; claims 1-48 were rejected as obvious under 35 USC 103(a) from Rioux (US patent 6,494,855) in view of Gellman (US patent application 2004/0078088); and claim 1 was provisionally rejected for double patenting over two co-pending applications of the Applicant.

Reconsideration of these objections and rejections is respectfully requested in view of this Amendment and Response.

Claims 1-48 are pending.

Restriction/Election

Claims 1-48 were elected without traverse in the Applicant's paper filed September 18, 2007. This paper was filed in response to the restriction requirement of August 22, 2007, which erroneously failed to include pending claims 88-91 in the restriction. The October 29, 2007 office action to which this Amendment and Response responds, also failed to address claims 88-91.

However, the August 22 restriction requirement attempted to deal with independent claim 88 and its dependent claims 89-91. On this basis, it is assumed that claims 88-91 were intended to be included in Group II of the August 22 restriction. It is on this basis that claims 88-91 had been canceled.

Applicant requests confirmation on the record that claims 88-91 were intended to be included in Group II in the August 22 restriction requirement. Otherwise, Applicant asserts the right to present cancel claims 88-91 in the prosecution of this application.

Information Disclosure Statements

Submitted concurrently with this Amendment and Response is a Ninth

Supplemental Information Disclosure Statement. The Applicant has recently discovered that Information Disclosure Statements which were filed on February 19, 2004, February 26, 2004, June 9, 2004 and June 15, 2004 are not listed in the PTO PAIR system records. This may have resulted from using an incorrect serial number (10/665,772) on those IDS's. It is expected that these prior IDS's can be viewed in Application 10/665,772. However, submitting the Ninth Supplemental IDS will assure consideration of the information contained in these previously filed IDS's. The fee under 37 CFR 1.17(p) has also been submitted in conjunction with the Ninth Supplemental IDS, to assure consideration.

In addition, the accompanying Ninth Supplemental IDS lists and attaches a copy of the reference W09116005 international (PCT), noted as missing in the October 29 office action.

Claim Objections and other Form Amendments

As shown above in Part 1, claims 1 and 31 have been amended to eliminate the basis for the objection and to improve clarity. In regard to claim 31, it now recites "movement of the indwelling catheter and the insertion tool **as** a unit within the urinary tract to the use position." This recitation is now clear.

The Examiner's attention to the form of the claims is appreciated.

In addition, other form discrepancies have been noted and corrected.

Claim 15 has been corrected at line 5, to recite a bridging "structure," which is used consistently throughout the claims and which distinguishes from the insertion tool that is also used consistently throughout the claims.

Claim 35 adds the word "is" to improve clarity at line 5.

Obviousness Rejection

Reconsideration of the obviousness rejection of claims 1-48 from Rioux in view of Gellman is respectfully requested. The October 29 office action includes approximately 16 separate comments alleging obviousness concerning claims within the group 1-48, and the following comments apply to all such separate comments.

It is respectfully submitted that independent claims 1 and 34 define patentable subject matter which is not obvious from Rioux and Gellman for the reasons discussed

below, among others. Likewise, the dependent claims 2-33 and 35-48 also define patentable nonobvious subject matter for the same and other reasons that independent claims 1 and 34 are not obvious.

A. Independent claim 1 -- Catheter

In the manner recited, claim 1 defines an indwelling catheter that drains urine from the bladder to a position distally adjacent to the urinary sphincter muscle. In this sense, the catheter drains the urine through the prostatic urethra. The catheter includes a main body with an interior urine drainage passageway. A balloon is attached to the distal end of the main body. The balloon expands within the bladder to restrain the main body against proximal or downstream movement. An inflation tube extends from the distal end of the main body through the orifice of the external urinary sphincter muscle and along the remainder of the urinary canal in the penis. The inflation tube delivers fluid to balloon to maintain its expanded condition, which is necessary since the indwelling catheter may be used over a considerable amount of time and it may become necessary to periodically reinflate the balloon since the balloon and the fluid passageways may experience minute fluid leaks, as explained in the application at page 13, line 28-page 14, line 5.

Claim 1 calls for a coiled section of the inflation tube to act as a restraint or anchor to prevent the main body of the catheter from moving further distally into the bladder. The coiled section of the inflation tube is located proximally or slightly downstream of the external urinary sphincter muscle. The coil interacts with the constricted urinary sphincter muscle to prevent or inhibit distal movement of the main body of the catheter into the bladder.

Thus, the inflated balloon within the bladder and the coiled section of the inflation tube downstream of the constricted urinary sphincter muscle hold the catheter in place to extend the main body through the prostatic urethra. The main body will not move distally into the bladder because of the restraint from the coiled section of the inflation tube, and the main body will not move proximally from the prostatic urethra into the urinary canal in the penis because of the restraint from the inflated balloon.

Neither Rioux nor Gellman teaches or suggests using a coiled section of an

inflation tube as a restraint against distal movement into the bladder. Indeed, neither Rioux nor Gellman contemplates using an inflation tube for two purposes, inflation and restraint. Further still, neither Rioux nor Gellman teaches or suggests simplifying and rendering more reliable, a catheter which extends from the bladder to the sphincter muscle by combining two previously-performed and separate functions (restraint and inflation) into a single component (coiled section of inflation tube).

The Rioux reference discloses an inflatable balloon in the bladder as a restraint for a catheter which extends through the prostatic urethra. Rioux also discloses an inflation tube. However, Rioux fails to recognize or suggest any benefit of restraint obtainable from the inflation tube, comparable to that improvement of claim 1. Instead, Rioux uses a separate downstream tube segment 20 as a restraint against proximal movement into the bladder, and the separate downstream tube segment 20 is entirely separate from and not related to the inflation tube. Consequently, Rioux uses a inflation tube only for purposes of inflation, and uses a second downstream tube segment only for the purposes of restraint. The two separate elements have their own separate and unrelated functions.

Rioux does not teach, recognize or suggest that the inflation tube may be used for any purpose other than inflation of the balloon. Rioux does not teach, recognize or suggest that the downstream tube segment may be used for any other purpose than restraint against distal movement. Consequently, Rioux certainly fails to teach, recognize or suggest that there is any beneficial improvement to be obtained by integrating the downstream restraint function with the inflation function in the inflation tube.

Gellman does not overcome the deficiencies of Rioux. Gellman is simply a coiled stent with one portion which holds open the prostatic urethra and another portion which is located downstream of the external urinary sphincter muscle to help hold the stent in place. The Gellman stent does not extend into the bladder, has no inflatable balloon, and therefore has no ability to restrain, within the bladder, against downstream or proximal movement. The Gellman stent has no inflation tube. Indeed, there is no fluid passageway of any type within the interior structure of the Gellman stent. The

interesting feature of Gellman is its biodegradable or absorptive exterior coating, because otherwise, coils of the type described by Gellman are very old in the art as shown by some of the references cited by the applicant.

Gellman is an entirely different type of urinary appliance from that described by Rioux. There is virtually no functional similarity between the two, except for the overall concepts which have been known for many decades of using an appliance to keep the prostatic urethra open under certain conditions.

A person having a skill in this art would not combine Rioux and Gellman, because they relate to entirely dissimilar types of appliances. Even if Rioux was combined with Gellman, the resulting combination would not teach or suggest the invention of claim 1, because such a resulting combination would simply substitute the downstream coiled section of the Gellman stent for the separate downstream tubular segment 20 of the Rioux catheter. Nothing about the proposed combination of Rioux and Gellman addresses or suggests the fact that the inflation tube can be used as a replacement for the separate downstream restraint.

The failure of the proposed combination of Rioux and Gellman to reach the scope and improvement of claim 1 demonstrates that Rioux and Gellman have been combined with hindsight gained from the present invention.

The only rationale asserted in the office action for combining Rioux and Gellman with respect to the catheter of claim 1 is that Gellman "provides the advantage of radial strength for a stent while conforming to a patient's anatomy" and the advantage of "anchoring a stent," and therefore a combination would "provide radial strength and anchoring for a urethral stent." See page 5, October 29 office action. These so-called advantages are not directly relevant to the invention, thereby further demonstrating the use of hindsight. Strength is not the principal issue of claim 1. A principle aspect of claim 1 is using the coil or other configuration of the inflation tube for restraint of the catheter. Nothing in Rioux or Gellman addresses this improvement.

Indeed, Gellman may not even provide strength, because once the exterior biodegradable coating dissolves it appears as though the device becomes weak, allowing it to be removed from the inside to the outside, i.e. distally to proximally, which

would be very difficult and/or very painful unless the device was significantly weakened. See Gellman's abstract which describes **temporary** structural support and facilitating **easy** removal. In contrast, the coils or other configuration in the inflation tube of the present invention must only have sufficient strength and rigidity to accomplish the described restraint function. See page 10, line 26-page 11, line 4.

There is nothing in Rioux or Gellman that addresses the improvement of using a configuration of the inflation tube to achieve restraint, thereby combining two functions into one structural feature and simplifying the catheter. The alleged advantages of the proposed combination of Rioux and Gellman are not significantly relevant to the significant improvement of the presently claimed catheter.

The nonobviousness of claim 1, discussed above, also applies with respect to dependent claims 2-33 and claims 43-47.

B. Independent claim 34, claims 10-19, 20-33, and 42-47 --
Catheter and Insertion Tool

These claims relate to the combination of a prostatic-length catheter with an insertion tool. Claims 10-19, 20-33 and 43-47 require the catheter to have the inflation tube with a coiled section of the inflation tube forming the restraint. Claim 42 requires a configuration section, rather than a coiled section of the inflation tube.

Because neither Rioux nor Gellman discloses, suggests, or otherwise reaches the subject matter of claim 1, the combination of an insertion tool with that subject matter fails to disclose, suggest or otherwise reach the subject matter of claims 10-19, 20-23 and 43-47. Therefore, these claims should not be obvious.

In addition, the recited separable connection of the main bodies of the catheter and insertion tool recited in claim 34, patentably distinguish the combination of the insertion tool and the catheter from Rioux and Gellman.

Independent claim 34 recites, in the manner set forth, an indwelling catheter, an insertion tool and a separable connection between the main bodies of the catheter and the insertion tool. The main body of the catheter extends from the bladder to the sphincter muscle. The separable connection is between the main body of the catheter and the main body of the insertion tool. The separable connection allows the main

bodies of catheter and the insertion tool to be moved as a unit when inserting the catheter for use into the prostatic urethra. However, the separable connection also allows selective separation of the main bodies of the catheter and the insertion tool. The separable connection feature is not disclosed or suggested by Rioux and Gellman.

The October 29 office action asserts that Rioux does not disclose an insertion tool. See October 29 office action, comment 14 at page 7. However, Rioux discloses that a “pusher may be used to advance the prosthesis up the urethra and into the bladder.” Column 9, lines 25-26. The details of such a pusher are not disclosed, but any such pusher would be required to interact with the second downstream anchor portion 20 of the catheter described in Rioux, not the main body portion 10. The interaction with the downstream anchor portion 20 would require it to be closely connected in an adjoining relationship with the prostatic portion 10 as described in Rioux at column 6, lines 49-54, because otherwise pushing would be impossible. Thus, any such pusher would necessarily have to interact with the downstream anchor portion 20.

Since one improvement of the catheter of claim 1 is to eliminate the separate downstream anchor portion, Rioux can not disclose or suggest that the pusher could establish a satisfactorily functioning separable connection with the main body of the catheter which extends through the prostatic urethra, because Rioux requires the intervening downstream separate anchor portion 20 for normal use functionality and therefore for insertion. Claim 34 does away with the need for a downstream anchor of the type described in Rioux.

The insertion tool of Gellman is shown in Fig. 3 and is described in paragraphs 47-52. As can be understood by comparing Figs. 2 and 3, a rotatable element 42 is inserted through the center of the windings 18 and 20. The end 39 of winding 20 is inserted into the hole 52 of the arm 46, and the other end 38 of the other winding 18 is inserted in the hole 62 of the other arm 58. Once in this position, the rotatable element 42 is rotated to twist the windings tightly and thereby reduce the outer diameter of those windings. The Gellman stent is inserted in this tightly coiled configuration. Once inserted, the ends 38 and 39 are disconnected from the holes 52 and 62, to allow the

stent to expand, and the insertion tool is removed.

The Gellman insertion tool requires connection to both ends of the stent. In addition, the Gellman insertion tool requires a downstream coiled segment to exist in order to connect with it, unlike the present invention which seeks to eliminate a downstream restraint as a separate component.

The insertion tools used in both Rioux and Gellman are thus vastly different in nature and operation from that recited in claim 34. Neither insertion tool interacts through a separable connection between the insertion tool and the main body of the catheter which extends only the prostatic urethra to the sphincter muscle. Both insertion tools in Rioux and Gellman require the use of the downstream restraint as a separate element to insert the appliance. The insertion tools described in both Rioux and Gellman are so vastly different in concept, structure and use, when viewed in conjunction with the catheters with which they are used, that they cannot realistically teach, suggest or otherwise provide any meaningful rationale for combining those references in a way which reaches the claimed requirements of the separable connection which interacts between the main bodies of the catheter and the insertion tool.

Certainly nothing in Rioux or Gellman discusses or suggests how the insertion tool should interact with the inflation tube or the coiled section of the inflation tube which surrounds the insertion tool, as recited in claims 10, 20 and 43, among others. Only Rioux discloses an inflation tube, but there is no discussion or suggestion of how it should interact with the pusher. Gellman does not use an inflation tube.

For these reasons, and others, it is respectfully asserted that the claims directed to the combination of the indwelling catheter and the insertion tool patentably distinguish from Rioux and Gellman. The lack of similarity in structure or function or relationship between the characteristics of the indwelling catheter and the insertion tool, as recited in the pending claims, demonstrates that the references were inappropriately combined with hindsight. Furthermore, even if the references were combined as asserted in the obviousness rejection, the combination does not meet the requirements and limitations of the pending claims.

C. Comments concerning Rationale and Motivation

Comments in paragraphs 10-13, 15, 20 and 23 in the October 29 office action appear to rely on strength of the coil or winding as the rationale for combining the references. As has been discussed above in part A, strength is not a principal motivating factor behind the downstream restraint, and such rationale for combining the references is therefore misplaced.

Comments in paragraph 14 in the October 29 office action appear to rely on the general and well-known concept of delivering a stent within a prostatic urethra as motivation or rationale for the combination. It is respectfully submitted that such motivation or rationale is so broad-brush and generic, and has been prevalent for so many decades, as to render such reasoning sufficiently non-specific to constitute any meaningful suggestion or rationale for combining references.

Comments in paragraphs 16, 18, 19, 21 and 24 in the October 29 office action appear to rely on the general concept of securing the indwelling catheter to an insertion tool. The rationale and motivation recited in these paragraphs appears to be so general and broad-brush as to not constitute a meaningful basis for combining the references as recited. Indeed, as discussed above in part B, the interaction of the insertion devices described in Rioux and Gellman with the characteristics of the catheters described in those references is so vastly different as to preclude any meaningful reason to combine the references, and moreover, even if the references were combined, the combination would not reach the scope of the claims.

The comments in paragraphs 17, 22 and 25 of the October 29 office action appear to provide no rationale whatsoever for combining the references, unless these comments are intended to allege that the subject matter recited in the claims is explicitly addressed in Rioux or Gellman. Clarification of the motivation or rationale for combining the references with respect to the claims noted in these paragraphs is respectfully requested, if those rejections are continued.

Provisional Double Patenting Rejection

As noted in the office action, there are two other co-pending applications of the Applicant directed to indwelling catheters: serial numbers 10/921,356, filed August 18,

2004 and 10/665,742, filed October 7, 2005. No subject matter has been patented in this or any other co-pending application, so it is believed that no response to this provisional double patenting rejection is required at this time. A response will be made at such time that there is an indication of allowable subject matter.

Conclusion

As a result of the amendments and remarks set forth above, it is believed that all pending claims in this application define patentable subject matter and are in condition for allowance. Allowance is respectfully requested. The Examiner is requested to contact the undersigned by telephone to discuss any issues which may inhibit the immediate allowance of the claims.

Any fees associated with this Amendment and Response may be charged to Deposit Account 12-1087.

Request for Telephone Interview

If the application is not allowable in view of this Amendment and Response, the Examiner is requested to telephone the undersigned for the purpose of setting a telephone interview to discuss the continued reasons for rejecting the claims of this application.

Respectfully submitted,

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